Office of Research Integrity

researchintegrity@fau.edu

<https://www.fau.edu/research-admin/research-integrity/human-subjects-irb/>

This Individual Investigator Agreement (IIA) serves as the mechanism under which FAU may extend the applicability of its FWA to cover collaborating *individuals and independent* *investigators* (those not covered by an institutional FWA or IRB). This Agreement is intended to be used for a single protocol. Prior approval from the Institutional Official or their designee is required for more than one collaborator to be named in an agreement.

**INSTRUCTIONS**: This document should be reviewed by both Individual Investigator and FAU Principal Investigator (PI). The FAU PI should upload a completed Individual Investigator Agreement into Novelution with the corresponding project. The PI’s signature and the signature of the Individual Investigator is required. The approval of this Agreement is contingent on the signature of the FAU Institutional Official.

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): Florida Atlantic University

Applicable FWA #: 00000157

FAU Principal Investigator:Click or tap here to enter text.

Specify Research Covered by this Agreement (Novelution number and Protocol Title):Click or tap here to enter text.

Individual Investigator Name:Click or tap here to enter text.

1. The above-named Individual Investigator has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; and 3) the relevant institutional policies and procedures for the protection of human subjects.
2. The Individual Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of the human subjects involved in research conducted under this Agreement.
3. The Individual Investigator will comply with all other federal, state, and local laws and regulations that are applicable to the protection for human subjects participating in research conducted under this agreement.
4. The Individual Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB. This includes the IRB’s responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Individual Investigator will provide all information requested by the IRB in a timely fashion. Failure to comply with the directives of the IRB may result in the Individual Investigator’s removal and/or termination from participating in the designated research activities.
5. The Individual Investigator will complete all training required by the Institution and/or the IRB prior to participating in the performance of research covered under this Agreement. The Institution and/or the IRB may require the Individual Investigator to complete training(s) over the course of the research project as deemed necessary.
6. The Individual Investigator will report promptly to PI any proposed changes in the research conducted under this Agreement. The Individual Investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. The Individual Investigator will report immediately to PI serious adverse events or unanticipated problems in in accordance with Policy 10.3.5, “Serious Adverse Event and Unanticipated Problem Reporting”.
8. The Individual Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by the IRB.
9. The Individual Investigator will report to the PI any pre-existing relationship with a potential subject, or group of potential subjects, the scope of any such relationship, and identify steps that will be taken to minimize any actual or perceived coercion or undue influence on and reduce potential for bias.
10. The Individual Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB and/or the FAU Institutional Official.
11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
12. This Agreement does not preclude the Individual Investigator from taking part in research not covered by this Agreement.
13. The Individual Investigator acknowledges that their primary responsibility is the safeguarding of the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.

Individual Investigator Name:Click or tap here to enter text.

Individual Investigator Signature: Date: Click or tap to enter a date.

FAU Principal Investigator Signature: Date:Click or tap to enter a date.

FAU Institutional Official Name: Gregg B. Fields, PhD

FAU Institutional Official or Designee Signature: Date:Click or tap to enter a date.